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Agence de réglementation de la lutte antiparasitaire

Regulatory Proposal

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Protection of Proprietary Interests in Pesticide Data in Canada

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Information Service:
1-800-267-6315 or 613-736-3799
Facsimile: 613-736-3758

Health Canada Santé Canada

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1.0 Introduction

In this Regulatory Proposal, Health Canada's Pest Management Regulatory Agency (PMRA) proposes new provisions for the protection of proprietary interests in data submitted to the PMRA in support of registration, re-evaluation and special review of pesticides, including technical grade active ingredients and their manufacturing concentrates as well as end-use products.

To ensure that the health and environmental risks as well as the value of the pest control products are acceptable, the PMRA requires that applicants submit pertinent scientific data. The proposal describes how data used to support and maintain registration of pest control products are protected and how they could be relied on subsequently by applicants for registration of equivalent technical grade active ingredients, manufacturing concentrates and end-use products.

Over the long term, the PMRA intends to develop regulations under the *Pest Control Products Act* that will prescribe the circumstances and conditions under which the information provided to the Minister is protected and how it may be used or relied upon by others than the initial registrants for applications or registrations.

This proposal would replace the provisions of Product Specific Registration (PSR) found in Trade Memorandum T-1-249, *Product-Specific Registration and Proprietary Rights to Data,* dated 8 July 1987.

2.0 Purpose and Context of Proposal

The current PSR provisions have been in place since 1987. Its stated objectives are to ensure that the safety, merit and value of products are supported to the maximum extent possible by modern databases, to promote a climate favourable to the introduction of new products in Canada, and to facilitate the registration of active ingredients from new sources, thereby ensuring the availability of competing pest control products.

Under PSR, the PMRA has played a pivotal role in protecting the proprietary interest in data submitted by the registrant in support of a technical grade active ingredient. PSR is a complex system that attempts to balance the needs of registrants[1], applicants[2] of generic products, formulators and vendors of products as well as users.

At the centre of PSR has been the determination of chemical equivalency (or biological equivalency for microbial pesticides) and the determination of the value of a registrant's protected data that an applicant wished to rely upon to support his subsequent registration petition for an equivalent technical grade active ingredient. To this end, the PMRA has applied a

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1 A registrant is an owner of a registered pest control product.

2 An applicant is someone seeking registration of a pest control product.

point-value system[3] to assign relative values to individual study types based on their financial cost. The process has been very resource intensive for the PMRA and has not generally been found satisfactory by most stakeholders.

This document sets out a proposal for a revised policy for the protection of proprietary interests in pesticide data (PPIP), which retains many of the elements of the earlier versions of PSR. The proposal incorporates the principle of chemical or biological equivalency, specifies categories of protected data and duration of data protection. However, in contrast to PSR, the proposal places the onus of determining data value and compensation on the companies involved.

The proposed PPIP policy is intended to encourage the introduction of new pesticides by protecting the innovator's substantial investment in a supporting database, thereby encouraging the availability of modern, innovative, potentially lower-risk products to Canadian users. On the other hand, the time limited nature of the data protection period will allow for introduction of equivalent products by generic manufacturers, thus enhancing market competition to the benefit of users, including growers. The proposal also includes incentives for adding uses identified on the Minor Use National Priority Listing through extended protection periods.

3.0 Overview of the PPIP

The proposed PPIP policy attempts to create a climate favourable to the introduction of new and reduced-risk pest control products, by protecting the investment in regulatory data made by innovator companies in supporting the registration of their products. This type of limited protection of regulatory data is common throughout the world and is included in international trade agreements such as the North American Free Trade Agreement s. 1711 and the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights s. 39.3.

In addition, the proposed PPIP policy aims to provide favourable conditions for generic pesticide producers to enter the pesticide market and to increase the selection of products available to the user.

The proposed PPIP policy is aimed at providing a clear direction for data protection, i.e., which data will be protected, to what degree and for how long they will be protected as well as a process by which generic producers can gain the right to rely on protected data.

This proposal first sets out the primary policy objectives and the principles that guided the development of the revised policy. It also describes which data will be protected, which protection status they will be assigned and for how long they will be protected.

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3 The point-value system of PSR II had been developed by the Crop Protection Institute of Canada, with input from the Canadian Manufacturers of Chemical Specialties, to assign relative value to databases. The points were then validated against a survey of contract laboratories conducted independently by the Pesticides Directorate of Agriculture Canada.

The proposal then describes the conditions under which and the mechanism by which the protected data may be accessed by an applicant desiring to rely on the registrants data.

The proposed transition from PSR to the proposed PPIP policy is described, as is a stepwise progression of the regulatory process that would apply to an application to register a generic product.

4.0 Major Elements of the Policy to Protect Proprietary Interests in Pesticide Data

4.1 Policy Objectives

The objectives of the proposed PPIP policy are as follows:

- A policy that provides fair protection of the proprietary interests in data to encourage the introduction of new and reduced-risk pest control products while providing a predictable, timely process for the introduction of competing generic pesticide products to the Canadian market.

- A policy that encourages registrants to seek registration of a wider range of pesticide uses that have been identified as important to Canadian users and that are listed on the National Minor Use Priority Listing.

- A policy that confers the determination of data value and compensation to the sphere of business decisions and agreements negotiated between the parties with regulatory guidance but without the direct participation and enforcement by the PMRA.

4.2 Guiding Principles

In establishing this PPIP proposal, the PMRA was guided by the following considerations:

- Technical grade active ingredients, manufacturing concentrates and end-use products must be found equivalent before reliance on an innovator registrant's database can be considered.
- Canada's obligations with respect to international agreements on data protection must be fulfilled.
- The PMRA approaches should be in close alignment with the United States Environmental Protection Agency (USEPA) general approaches to data protection and access of generic applicants to protected data.
- Rules and processes for the PPIP policy should be clear and simple, and the process and rules for negotiations should be transparent and predictable.
- Unnecessary, duplicative animal testing should be avoided.
- All registrations must be supported by relevant health, environmental and value data.

4.3 Data Protection

4.3.1 Application of the Policy

The PMRA will apply the PPIP policy when an applicant requests to register or amend the registration of a technical grade active ingredient, manufacturing concentrate or end-use product relying wholly or in part on data of another company with a registered product.

When an applicant copies an end-use product based on a technical grade active ingredient, manufacturing concentrate or an end-use product purchased from a registered source, and this registered source confirms this to the PMRA in writing via a Letter of Confirmation, the Agency will grant access to the protected database without further consideration of protection status. The PMRA assumes that the access to the protected data and the compensation have been part of the business agreement between the registrant and the applicant.

4.3.2 Protected/Non-Protected Data

Under the proposed PPIP policy, the proprietary interest in the following data will be protected:

- Data submitted to the PMRA by the first registrant and that formed the basis for registering the technical grade of a new active ingredient and its associated end-use product and/or manufacturing concentrate.

- Data submitted to the PMRA after the first registration of a technical grade active ingredient, an end-use product or a manufacturing concentrate and that formed the basis for additional/amended registration or the maintenance of a registration, i.e., data submitted for use expansions, new formulations, updating of existing data.

- Data requested by the PMRA as a condition of registration and data requested under sections 12(1), 16(3) and 18(1) of the *Pest Control Products Act*, which were part of the data used by the Agency in arriving at re-evaluation or special review decisions.

  The proprietary interests in these data will be protected for specified periods of time (see Section 4.3.4) and may be relied on by applicants only under specified conditions.

The following data will not be protected:

- Data that are in the public domain, e.g., data published in the open literature.
- Research and monitoring data generated in Canada by federal and provincial government bodies, or international regulatory bodies such as the World Health Organization.
- Data that the PMRA deemed to be invalid for regulatory purposes.
- Data not requested by the PMRA and not considered for a registration decision.

4.3.3 Classification and Protection Status of Data

Databases will be assigned a protection status based on their nature, the regulatory context of submission and their use in making registration decisions.

The PMRA proposes to assign a protection status to an entire database rather than to identify and assign a protection status to individual studies within a database. A database could only have one of the following protection status.

Exclusive Protection Status
Data submitted to the PMRA and that formed the basis for registering the technical grade of a new active ingredient and its associated end-use product or manufacturing concentrate are classified as original data and will be given an exclusive protection status. Also included in the exclusive category will be all data considered in the decision for continued registration, i.e., data submitted by a registrant following a PMRA's request to fulfill a condition of registration related to new technical grade active ingredient.

An exclusive protection status will be given for a specified period during which it cannot be used by an applicant without written consent from the first registrant. During the exclusive protection period, the registrant (owner of an original database) can voluntarily, but is not obliged to, enter into negotiation with an applicant for access to and compensation for a database under exclusive protection.

Compensable Protection Status
Data submitted to the PMRA subsequent to the first full registration of a new technical grade active ingredient, and its accompanying end-use product or manufacturing concentrate are assigned a compensable protection status. These are data that formed the basis for an additional/amended registration or maintenance of a registration, i.e., data submitted for use expansions, new formulations, data requested under sections 12(1), 16(3) and 18(1) of the *Pest Control Products Act* submitted to and considered by the PMRA in the context of re-evaluation and special review. It should be noted that a compensable protection status starts only once the exclusive protection status of a database has lapsed.

A compensable protection status will be given for a specified period of time during which an applicant can gain the right to rely on a registrant's database by entering into a negotiated commercial agreement that addresses the issue of data access and compensation of the owner of those data.

The owner of the compensable database will be obliged to negotiate with an applicant and, if necessary, binding arbitration may be used for a final resolution of access and compensation issues.

Non-Protected, Generic Status
The PMRA will consider any database that does not meet the criteria for exclusive or compensable protection status, or whose exclusive or compensable protection status has lapsed, to be without protection.

4.3.4 Protection Periods: Start and Duration

A database that qualifies for an exclusive protection status will be given 10 years of exclusive protection from the date of first registration of a TGAI. This period can be extended incrementally up to five years with the addition of uses that have been listed on the Minor Use National Priority Listing.

In order to encourage and to set a regulatory climate favourable to adding minor uses, the PMRA will extend the exclusive protection period by one year for each addition of three minor uses crops to the label. In the case of crop grouping, only the representative crops tested in support of a crop grouping will be counted as new minor crops, the additional crops in the crop grouping will not be counted. The Minor Uses crop and pest combination must be listed on the Minor Use National Priority Listing and the supporting data must be provided by the registrant.

In order to qualify for an extension of the protection period, applications to add minor uses to the existing uses must be submitted at least two years prior to the expiry of the exclusive protection period in order to allow sufficient time for regulatory review and decision. The maximal exclusive protection period will be 15 years.

A database that qualifies for a compensable protection status will be given 12 years of compensable protection from the date of the original application for a use expansion or a change of formulation, and from the date of submission when providing data in response to a PMRA request under sections 12(1), 16(3) and 18(1) of the *Pest Control Products Act* in support of re-evaluation or special review decisions.

The compensable protection period cannot be extended by providing new data that are comparable to previously submitted data.

Once an applicant has been granted the right to rely on a database under exclusive or compensable protection, this right cannot be revoked.

4.4 Access to Protected Data

4.4.1 Negotiation/Arbitration

During the period of exclusive and compensable data protection, an applicant can acquire the right to rely on a protected database through negotiation with the owner of the database. Applicants can also submit data comparable to the protected data, but such data would not be granted protection exceeding that of the original protection period.

Negotiation of access to a database under exclusive protection status will be strictly voluntary on the part of the owner of the data. The PMRA will take no part in these commercial negotiations and will consider an application for registration only upon receipt of a written communication of the business agreement giving the right to rely on the protected database.

Negotiation of access to a database with compensable protection status will be mandatory. The *Pest Control Products Act* sections 66(1) and 66(2) require that the Minister determine the terms and conditions of agreements to be entered into by registrants and applicants for the purpose of determining compensation payable for the right to use or rely on information provided by registrants to the Minister under the Act. Section 66(2) further requires that such an agreement be arrived through negotiation and binding arbitration, in accordance with regulations made under section 67(1)(h). The Act further stipulates that for the purpose of the regulation the *Commercial Arbitration Act* shall be used.

The PMRA intends to implement these provisions of *Pest Control Products Act* and will develop a regulation within a reasonable time. The regulation will set out the principal parameters for negotiation and binding arbitration.

The PMRA will assist the registrant(s) in identifying which data are included in the compensable database, but will take no part in the negotiations between applicant and registrant(s). It should be noted that although a complete list of protected data will be identified, the two parties may negociate for a subset of the data. However, the PMRA will not enforce this agreement on behalf of the registrants. It is expected that both parties will be actively monitoring compliance with their business agreements.

If there is more than one registrant of an equivalent technical grade active ingredient, the applicant must obtain access to a complete set of data required by the Minister through negotiation with either one registrant with a complete set of protected data or a combination of registrants each having subsets of the protected data.

Once the PMRA has established the equivalency and has identified which data are protected, the applicant and registrant(s) will be required to enter into mandatory negotiation for data access and compensation. The time allocated for negotiation will be 90 days. If, after an initial 90 days of negotiation, both parties agree that a negotiated settlement can be achieved, they can extend the negotiation period for another 90 days to allow for completion of the negotiation. If, after the initial 90-day negotiation period, a negotiated settlement appears to be unachievable, either party may initiate binding arbitration for a period of 90 days.

It should be noted that the PMRA will not get involved in the negotiation process. The PMRA will close the application file once the protected data has been identified and prior to the 90-day negotiation period. The PMRA will restart the registration process only upon completion of the negotiation/arbitration and receipt of a new application accompanied by a written confirmation granting the applicant the right to access the registrant's data.

In the case of failure of a registrant to participate in the negotiation or arbitration, or refusal to comply with the terms of the arbitration, the PMRA will rely on the registrant's data in support of the applicant's petition.

4.4.2 Start of Registration

The proposed mandatory negotiation and binding arbitration process is designed to ensure resolution of data compensation issues within a prescribed and reasonably short-time period.

The PMRA has considered whether a generic pest control product could be given registration status prior to the mandatory negotiation period, i.e., as soon as its equivalency has been established and the protected data have been identified, or whether its registration should only be granted after the negotiation/arbitration process has been completed.

Granting registration immediately would be similar to the approach taken by the USEPA. However, since this proposal would set short time lines for mandatory negotiation/arbitration, the PMRA proposes to proceed with registration after completion of the negotiation/arbitration process.

4.5 Transition From PSR II to the PPIP

The new PPIP policy will not revoke any proprietary interest protection of data previously granted under PSR II. These data will continue to be protected and the new protection periods will be applied once the PPIP policy comes into effect. However, with the publication of this proposal, the PMRA gives notice that protection of data submitted voluntarily will now only be considered if the data is needed for the continuing support of a current registration.

Once the PPIP policy will be in effect, registrants may extend an existing exclusive protection period by adding uses listed on the Minor Use National Priority Listing as described in Section 4.3.4.

Applications by generic manufacturers to register pest control products in reliance on a protected database will continue to be processed according to Trade Memorandum T-1-249 (PSR II) until the new policy will come into effect.

4.6 Re-evaluation and Special Review

4.6.1 New Registrations

Applications to register a new TGAI, MA or EP based wholly or in part on data of an already registered pest control product while that product is under re-evaluation or a special review provides a particular challenge to the protection of data ownership.

Once the re-evaluation of a pesticide has been initiated, an applicant, having obtained access to the protected data through negotiation/arbitration with one or several registrants, will also have to

satisfy all data requirements that may be imposed on the original registrant(s) as condition of continued registration.

4.6.2 Existing Registrations

For re-evaluation and special review purposes, it is assumed that all registrants either had to provide their own data, or had to gain access to another registrant's database in order to be granted registration. Therefore, the PMRA uses all available data and applies them to all registrants for evaluating their acceptability for continued registration.

However, it is frequent that part of the data have been submitted by only some of the registrants to support specific uses or claims for some, but not all products. If other registrants, or an applicant, wish to rely upon these data in order to add new uses or claims to his product, they would need to negotiate with the original submitter of these data to gain access.

If the PMRA requires new data as a condition of continued registration, these requirements will have to be satisfied by all relevant registrants. Registrants may develop the data individually, together with others, or they may gain access to another registrant's data as per section 4.4 of this proposal.

4.6.3 Program One of Re-evaluation

The USEPA Reregistration Eligibility Documents (REDs) are frequently used by the PMRA in support of re-evaluation decisions under Program One as per Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*. REDs are based on data submitted to the USEPA. The actual studies are not submitted to the PMRA, but are considered to have been relied on and may be subject to data protection.

The data identified in the USEPA RED will be protected in the context of a new registration if the following criteria are met:

- The active ingredient is or was re-evaluated under Program One.
- The data is considered relevant to the Canadian use pattern.
- The data has no equivalent in the PMRA's database.
- The data is less than 12 years old.
- The registrant can demonstrate ownership of the data.

Appendix I

Comparison of Data Protection under PSR II, the PPIP and the USEPA

	PSR II[a]	PPIP Proposal	USEPA[b]
Exclusive protection status	Technical grade active ingredient only	Technical grade active ingredient, end-use product and manufacturing concentrate	
	10 years from first registration	10 years from first registration Extension by 1 year for each 3 minor uses for up to 5 additional years. Minor uses must be submitted 2 years prior to the expiry of the exclusive protection period	10 years from first registration Extension by 1 year for each 3 minor uses for up to 3 additional years; Minor uses must be added prior to the 7th year of registration
Compensable protection status	15 years from date of study (does not apply to original data)	12 years from the date of the original application for a use expansion or a change of formulation 12 years from the date of submission for data provided in support of re-evaluation or special review decisions.	15 years from submission (includes original data)
Access to data with compensable protection status	Generation of new data based on point-value system	Mandatory negotiation/binding arbitration between applicant and registrant(s) for access and compensation	Mandatory negotiation/binding arbitration between applicant and registrant(s) for access and compensation

[a] Trade Memorandum T-1-249 (Policy)

[b] *Federal Insecticide, Fungicide and Rodenticide Act* and Part 152 E (Regulations)